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# **Heterogeneity in learning processes and the evolution of dynamic managerial capabilities as a response of emergence of biosimilar market: Evidence from the Indian pharmaceutical industry**

## **Abstract**

This paper examines heterogeneity in the response of Indian firms to the emergence of a new segment in the pharmaceutical generics market - biosimilars. The necessary diversity of the knowledge base and regulatory requirements underlying biosimilar products have created significant technological capability and market access challenges for Indian firms. This is but the latest development which adds to an existing catalogue of challenges including the decline of the traditional generics markets, regulatory hurdles in advanced country markets and failures in managing new drug development. Using case studies of three Indian firms we show that dynamic managerial capability is a key driver of heterogeneity in learning processes involved in acquisition of technological capabilities for biosimilars and market access strategies. It further highlights the important role of pre-existing capabilities in enabling and constraining the development of new biosimilar capabilities.

**Key words:** India, dynamic capabilities, pharmaceutical industry, heterogeneity

## **1.0 Introduction**

In the last two decades, the ways firms respond to changes in the external environment has emerged as a major concern of the dynamic capability and industry evolution literature (Helfat and Winter, 2011; Teece et al., 1997). In response, Adner and Helfat (2003) highlight the impact of managers on strategic change by presenting the dynamic managerial capabilities concept – the capacities with which managers create, extend and modify the ways in which firms respond to change. To a large extent, the dynamic capability and dynamic managerial capability literature has focused on firms in advanced countries. In developing countries, however, the challenge for firms is more demanding as local technological, political and economic realities complicate the transformation of capabilities (Amann and Cantwell, 2013). This paper addresses a gap in the current literature by investigating response of Indian pharmaceutical firms to the emergence of a market for biosimilars.

Biosimilars are generic versions of biological drugs. The market for biosimilars is growing and represents a significant opportunity for the Indian biotech and pharmaceutical industries. The complexity of biological drugs and extensive regulatory requirements however, has meant both challenges and opportunities for developing country firms (Huzair and Kale, 2011). In this context, the Indian pharmaceutical industry provides us with informative case studies with which we may explore the development of dynamic capabilities by resource-constrained firms.

Post 2000, the Indian pharmaceutical industry emerged as a global supplier of cheap generic drugs. A decade on, increasingly competitive generic markets in advanced countries are witnessing a significant drop in value (Kamath, 2011). For leading Indian firms this market challenge is further compounded by regulatory hurdles in advanced country markets and failures in managing new drug development, raising important questions for long-term growth and survival. This gives rise to the key research question; how are firms reconfiguring their strategies for the development of capabilities in response to the emergence of biosimilar market opportunities?

Using case studies of three Indian firms we show the heterogeneity in firms' reconfiguration strategies and further explore the origin of heterogeneity when different firms operate in the same environment with the same resource base. Our paper makes three critical contributions to the dynamic capabilities and industry evolution literatures. First, it demonstrates how a change

in market re-orientates technological capabilities even in the absence of a radical technological discontinuity. Second, the paper shows dynamic and managerial capabilities applied to three areas; diversification of the knowledge base, technological (production) capability and regulatory affairs. The distinction between dynamic capabilities and managerial capabilities can be difficult to do in practice, but is attempted by this work as we draw that distinction and demonstrate how they interact. Third, this paper demonstrates how pre-existing technological capability which served small molecule generic markets, are not necessarily abandoned. In this case, where significant risk and uncertainty exists, achieving a balance between generics production and investment in biosimilars is key to survival in the short term.

This paper is structured as follows: Section 2 reviews key literature on heterogeneity and the dynamic capabilities approach. Section 3 explains the salient features of the Indian pharmaceutical industry and challenges to existing business models. Section 4 discusses size and growth of the biosimilar market, and tracks the challenges of the biosimilar capability development for emerging country firms. Section 5 details our data collection methods and the three Indian pharmaceutical firm case studies that are used to illustrate the evolution of firm strategy and biosimilar R&D capability. In section 6 we present our results on the different strategies and the reconfiguration of capabilities of Indian pharmaceutical firms in response to market opportunities. Section 7 concludes.

## **2.0 Firm strategies and dynamic capabilities**

Firm capabilities were explored as early as 1959 in the works of Penrose who suggested that the growth of firms is conditioned by their resources and the desire to fully exploit them. Helfat and Winter (2011: 1244) define capability as “the capacity to perform a particular activity in a reliable and at least minimally satisfactory manner”. Highlighting connection between objective, purpose and an intended outcome, Dosi et al. (2000:2), suggest “capabilities fill the gap between intention and outcome, and they fill it in such a way that the outcome bears a resemblance to what was intended”.

Firm capabilities evolve over time as firms encounter endogenous market changes and exogenous shocks (Athreye et al., 2009). In markets where the competitive landscape is continuously shifting, dynamic capabilities become the source of competitive advantage (Teece et al., 1997). Here ‘dynamic capabilities’ refer to the “firm’s ability to integrate, build and

reconfigure internal and external competencies to address rapidly changing environments” (Teece et al., 1997:516). These capabilities are rooted in high performance routines operating inside in the firm, embedded in firm’s processes, and are conditioned by its history.

Eisenhardt and Martin (2000) add that dynamic capabilities are a set of identifiable processes including product development, strategic decision-making and alliancing, which are path dependent. Following from this, Adner and Helfat (2003) introduced the concept of dynamic managerial capabilities to help explain the relationship between managerial decisions and actions, strategic change, and corporate performance under conditions of change. This strand of research extends the dynamic capabilities perspective by understanding the role of managers both as individuals and within teams (Helfat and Martin, 2015). Helfat and Martin (2015) explicitly link heterogeneity in firm’s performance and strategies with firm specific dynamic managerial capabilities. They emphasise the influence of the ‘asset orchestrating’ role-played by firm specific managerial capabilities in shaping strategic change. However, Helfat and Martin (2015) suggest that these strands of the literature have failed to explore how interactions between dynamic managerial capabilities and resources, influence strategic change.

Relatively few studies on emerging countries have attempted to explain variability in latecomer firms’ strategies and dynamic capabilities (Amann and Cantwell, 2013) or the building of firm level innovative capabilities (Mathews, 2006; Kim and Nelson, 2000). Bell and Figueiredo (2013) argue that the study of dynamic capability development in latecomer firms has been limited and under researched except for Amsden and Tschang (2003), Dutrenit (2000) and Athreye et al. (2009). This paper builds-on and adds to the research focused on the evolution of dynamic managerial capabilities in emerging country firms by focusing on Indian firms’ responses to the emergence of a biosimilar sector.

This paper goes beyond establishing a descriptive portrait of firm level processes involved in the development of technological capabilities to engage with the question of how different strategies and therefore capabilities arise in emerging pharma firms, despite common constraints.

### **3.0 The Indian pharma-biotech industry**

The Indian pharmaceutical industry ranks 12th in the world in terms of value and by volume is the second largest in the world. In last few decades, Indian pharma industry emerged as ‘pharmacy of the world’ by dominating small molecule generic markets using their superior process R&D skills, cheap production processes and strong marketing capabilities (Kale and Wield, 2008). In recent years, however, the Indian pharmaceutical industry has faced key challenges such as a significant decline in value of small molecule generics markets, increased regulatory scrutiny by the FDA and the high rates of failure associated with bringing innovative drugs to market. In this context, biosimilars presented an opportunity for growth and diversification. The significance of biosimilars is explained by the R&D head of a leading Indian firm;

“Biosimilars are extremely important in two dimensions: from a very local healthcare market perspective this class of drugs are very influential in management of human health disease. This is critical from a simple perspective of making medicines available to people. From a more global perspective how does Indian pharma compete and where is that we continue to be relevant in the global industry to me this clearly represents one of the areas that we must move towards.”

For resource constrained Indian firms this significant shift in global generics markets will demand a new set of R&D, regulatory and marketing capabilities.

#### **4.0 The emergence of a new market: Biosimilars**

The growth in the biosimilar market is driven by several factors including original biologics coming off patent, pressure on governments to reduce healthcare costs and development of regulatory guidance in key markets. Biologicals account for an increasing portion of newly approved therapies for chronic inflammatory diseases, arthritis and cancer and biosimilars are poised to acquire a significant share of the generics pharmaceutical market (Wechsler, 2011). Switching to biosimilars is not an easy, minimum risk strategy, but a decision that requires considerable financial and organisational investment in developing regulatory, technical and scientific capabilities. The technical competencies that are required to manufacture biologics and biosimilars include abilities to generate pharmacovigilance and bioequivalence data.

##### **4.1. The challenge of a knowledge base**

Over the years Indian pharma firms have developed a knowledge base firmly embedded in organic and synthetic chemistry. In the case of biosimilars, these firms need expertise to reverse-

engineer biologics and develop stable, therapeutically active cell lines. Attempts to create a generic version of a reference biologic is likely to produce a product with some degree of variation. Understanding the possibility and consequences of even small variations require knowledge in new fields of biology. Firms producing biosimilars also need to develop manufacturing processes to meet specifications and to invest in new infrastructures for controlling living cells, purification, and producing biologic products consistently at commercial scale (Lee et al., 2011). The main constraint for Indian firms is the lack of expertise in areas of biology and biotechnology pertinent to biosimilars. A senior scientist in Serum Institute of India explains;

“In biosimilar development it is quite hard to spot small differences in production processes. These can lead to significant changes to drug safety and efficacy. But in India there are very few people who have this knowledge.”

#### **4.2 The challenge of regulatory requirements**

Indian firms are also facing the challenge of developing biosimilar focused regulatory capabilities. Regulatory frameworks particularly in advanced country markets, demand extensive data on clinical trials and immunogenicity. The evolving nature of regulation, is creating financial and technological capability challenges for Indian firms. The head of R&D in an Indian firm comments,

“I mean everybody sees the biosimilar opportunity but the question is how many can do it. The key question is how many firms in India can create their own teams that can develop biosimilars globally? I will separate the ability question from the funding question. In many ways, the funding question is easier to answer than the ability question.”

#### **5.0 Strategy and dynamic capabilities: Case studies of three firms**

The Indian biosimilar market is worth around US\$380 million and has been growing at a CAGR 30% since 2008 (Huzair and Kale, 2015). There are approximately 20 Indian firms with technological capabilities in the manufacture of recombinant products and these may foreseeably produce biosimilars (GABI, 2015). To explore Indian firms’ strategies, we will present case studies of three Indian pharmaceutical firms (Table 1).

**Table 1 Firms studied in the present research (Annual Reports, 2013)**

<b>Firms</b>	<b>Nature of firm</b>	<b>Turnover 2012-13 US \$ mn</b>	<b>R&amp;D intensity (2013)</b>	<b>Biosimilar</b>	<b>Supply of Biosimilar in overseas market</b>
Biocon	Biotech	364.16	10% (US \$ 36.4 mn)	Human insulin, Insulin Glargine, Erythropoietin, Filgrastim, Streptokinase, Itolizumab, Transtuzumab	27 countries
Cipla	Pharma	1545.00	4.9% (US \$ 79.5 mn)	Etanercept, Darbepoetin alfa'	India
DRL	Pharma	1560.00	6.6% (US \$ 143.6 mn)	Filgrastim, Rituximab, pegfilgrastim, darbepoetin alpha	12 countries

Primary data for the case studies was collected through interviews with R&D presidents, senior scientists and heads of biotech R&D in the three firms. We also conducted interviews with a key member of the Indian pharmaceuticals industry association and with a senior sector specialist journalist. Data was triangulated by using information in annual reports, analysts' presentations and articles in the business press. Interviews focused on firm strategy, challenges and organisational learning activities involved in the acquisition of new knowledge required for biosimilar development, the relevance of existing pharmaceutical R&D and manufacturing in the development of biosimilar capabilities.

Our reasons for focussing on these firms are threefold. One, the firms selected for study are in different stages of developing biosimilar product portfolios and thus provide ideal cases to study the reconfiguration of firm level capabilities. Biocon and DRL are early entrants while Cipla is a late entrant. Second, these cases provide a mix of different types of Indian firms with biosimilar capabilities; pharma firms (Cipla), biotechnology dedicated firms (Biocon) and pharma-biotech firms (DRL). This allows us to examine the significance of path dependency, differences in strategies and the role of established routines in the reconfiguration of capabilities. Third, all these firms are family owned businesses with strong leaders, thus

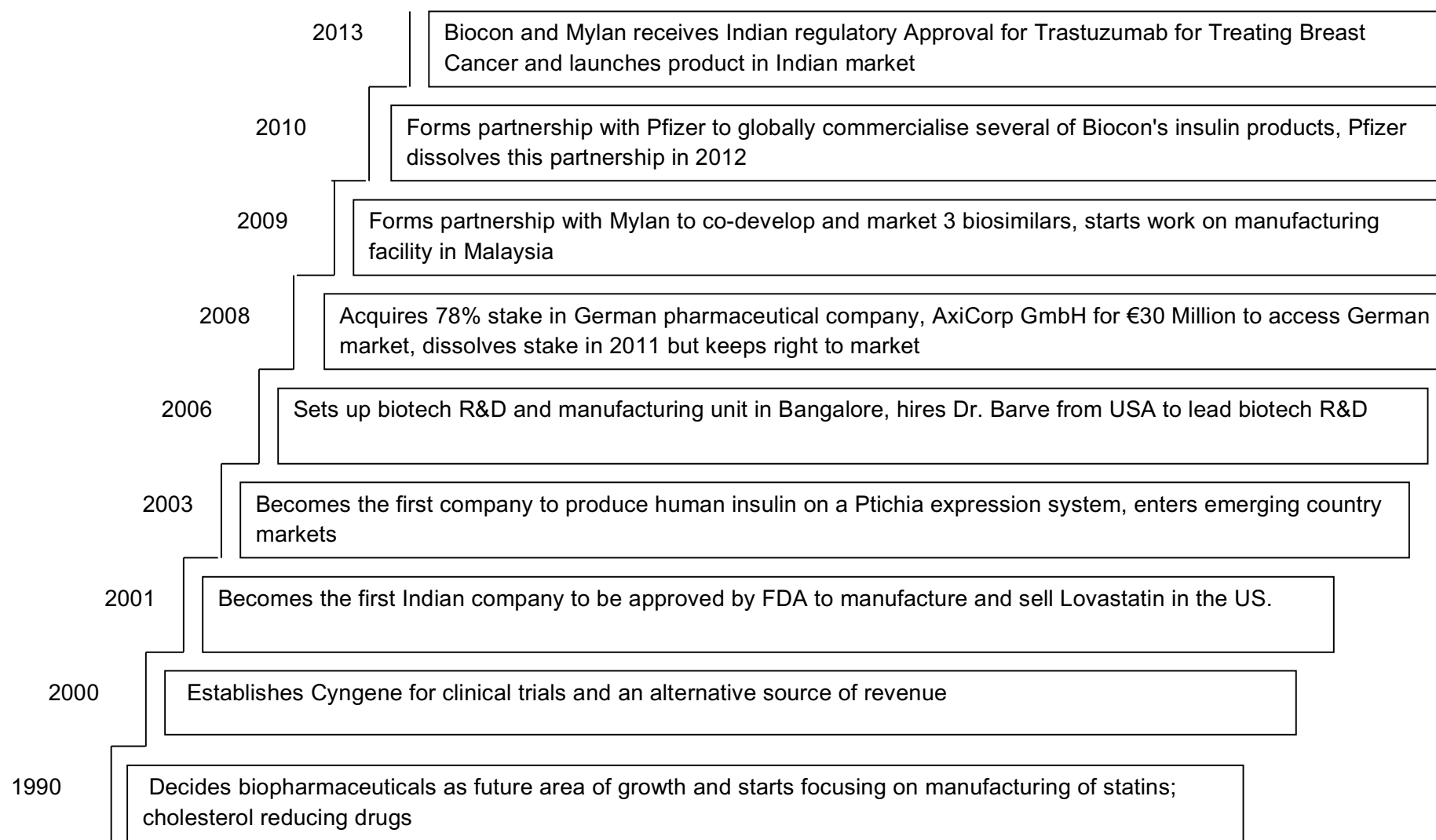


providing an opportunity to track influence of managerial capabilities on strategic change and heterogeneity in learning processes. The firms under study are not representative of the whole pharmaceutical industry. The study is not intended to extrapolate beyond that fraction of the industry which is dedicated to the manufacture of biologicals. These firms do however exemplify how firms in emerging countries develop more sophisticated capabilities in biological production from a basis generics production or biotechnology. We argue that this study is important not only because it demonstrates what will be happening in other emerging countries but because biosimilar producers can potentially and significantly impact the costs of health care globally.

### **5.1 Biocon: The dedicated biotech firm**

Hot on the heels of US biotech firms like Genentech, which for the first-time cloned insulin in 1978, Biocon was established in 1978 by Kiran Muzumdar Shaw. Her aim was to develop a fully integrated biotechnology company focused on biopharmaceuticals, custom and clinical research. In 1979 it became the first Indian company to manufacture and export enzymes to the US and Europe. Throughout 1990s, however, the company maintained its focus on biopharmaceuticals and set up an in-house biotech research programme. The main milestones in the company's biosimilar capability development are summarised in fig 1.

**Fig 1 Biocon Laboratories**



2006 marks a crucial point in the company's history, with the development of a more sophisticated biosimilar strategy to target cancer. 8 years prior, Genentech had launched a first-in-class monoclonal antibody therapy for breast cancer, Herceptin (Trastuzumab), which proved to be extremely profitable. With patent expiration in 2014 in Europe and in 2019 in the US, Biocon identified the potential for a biosimilar to compete in this area and developed capacity accordingly. In 2006 Biocon established India's largest multi-product Biologicals R&D facility in Bangalore, focusing on diabetes and oncology. The company filled knowledge gaps through collaborative R&D partnerships and by building a strong, focused research team. In 2006 Biocon entered a joint venture with the Cuban Institute of Monoclonal Antibodies to develop cancer therapies, followed by a joint venture with Abraxis Bioscience to develop a biosimilar version of Filgrastim (commonly used in oncology) in 2007. In the same year, Biocon hired Dr Barve from a US biotech firm to lead its clinical research division and later to head biotech R&D. Under his leadership, Biocon adopted an aggressive strategy of targeting overseas markets through various collaborations and joint ventures (Fig 1). In 2009 Biocon formed a strategic joint venture with Mylan, an MNC generics firm, to co-develop four biosimilars and enter the global biosimilar market. In 2013, the Biocon – Mylan partnership achieved its first success with regulatory approval for its own version of Trastuzumab.

Biocon's successful growth into a fully integrated biotech company with a strong biosimilar portfolio and an extensive presence in international markets was founded on a targeted programme of organic growth and investments in biotech R&D. It showed a good foresight in grasping the significance emerging biosimilar markets long before other firms. In expanding its R&D capability the firm paid attention to human resource recruitment to fill knowledge gaps and initiate collaborations to enter international markets.

## **5.2 Cipla: A traditional pharmaceutical firm**

Cipla (**Chemical, Industrial and Pharmaceutical Laboratories Ltd**) was established in 1935 by Dr A K Hamied and emerged as a leader in the 1970s with its ability to reverse engineer patented molecules, successfully launching low priced generics in India. Over the last five decades Cipla developed extensive capabilities in process R&D and has emerged as a global supplier of cheap generic drugs. Cipla transformed the global HIV-AIDS treatment landscape by launching antiretroviral drugs in emerging countries at comparatively low price. It gave

boost to Cipla's international generics strategy and by 2012 emerged as one of the most successful Indian firms with an average annual growth rate of over 20%.

In post TRIPs era, the transformation of the Indian domestic market and increased competition from global generic manufacturers forced Cipla to embrace biosimilars as a key area of future growth. But to achieve success in the biosimilar market, Cipla faced major hurdles in the form of R&D and manufacturing capabilities and lacked the professional management required to manage international expansion in the emerging biosimilar market. To overcome these knowledge gaps Cipla embarked on a two-pronged strategy (fig 2). First it acquired biotech firms and entered inward co-licensing deals. Second, it created management teams experienced in international expansion by hiring senior management professionals from competitor MNC firms.

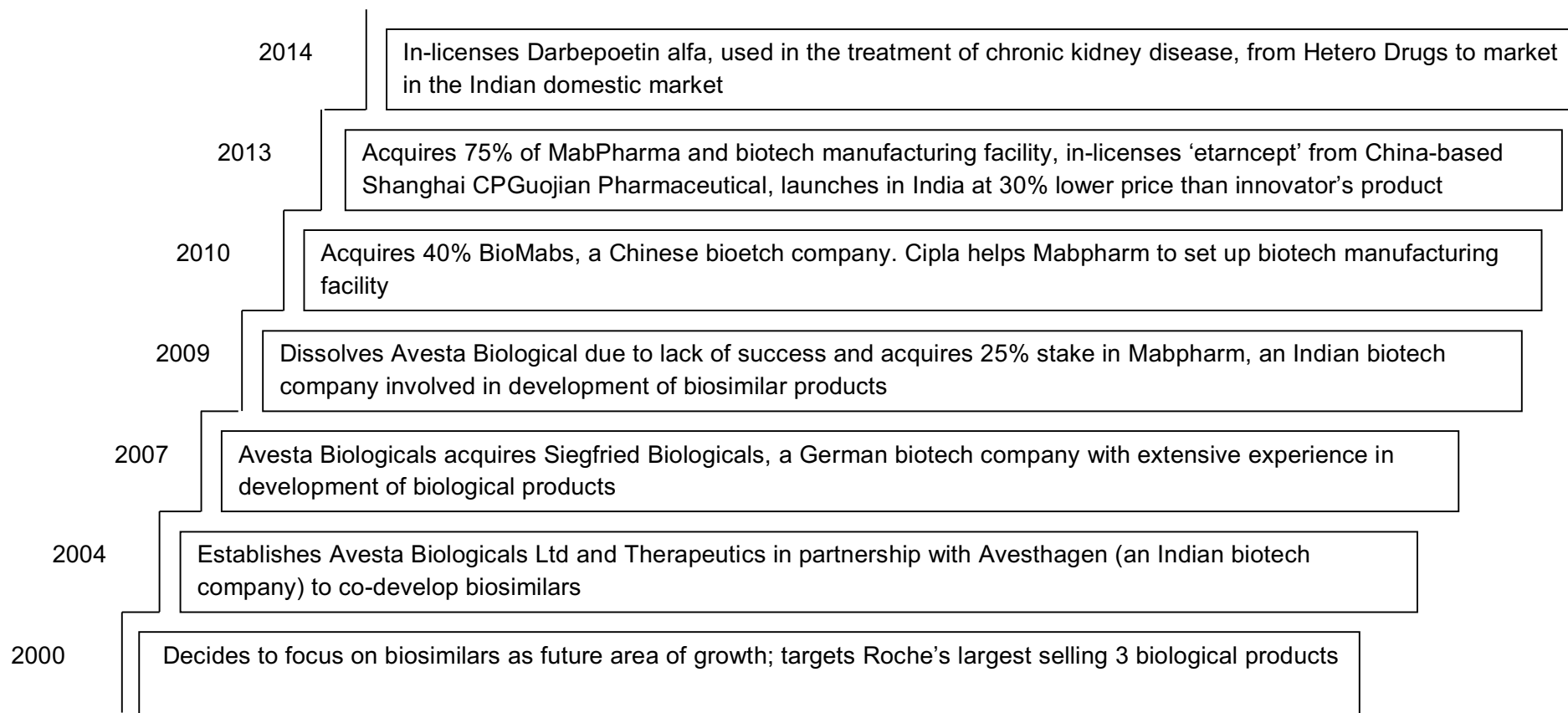
To accelerate biosimilar development in 2004 Cipla created Avesta Biologicals Ltd, a new biotech company in partnership with Avesthagen, an Indian biotech company. Avesthagen was responsible for biosimilar R&D while Cipla's role was to scale-up and manage sales and distribution in domestic and international markets. In 2007, Avesta Biological acquired Siegfried Biologicals, a biotech company based in Germany, to access biological R&D expertise. Siegfried was a contract-manufacturing company with experience in the development of biologicals including cell line generation, upstream process development and scale-up of manufacturing processes that comply with Good Manufacturing Practices (GMP). However in 2009 Cipla decided to dissolve Avesta Biologicals and Therapeutics due to lack of progress in biosimilar development.

To overcome this failure, in 2010 Cipla acquired a 25% stake in MabPharm, an India based biotech firm. In 2011, Cipla helped MabPharma set up a state of the art biotechnology manufacturing facility in India and in 2014, Cipla gained full ownership of the manufacturing plant by acquiring the remaining 75% share. In parallel to the MabPharm acquisition, Cipla invested \$65 million to acquire a 40% stake in Bio Mabs, a Shanghai based biotech aimed at developing ten monoclonal antibody drugs and fusion proteins for rheumatoid arthritis, cancers and asthma for marketing in India and China.

To complement these acquisitions, Cipla decided to build a biosimilar product portfolio through in-licencing. In 2013, Cipla launched its first biosimilar product, Etanercept, through in-licensing from China-based Shanghai CP Guojian Pharmaceutical Co. In 2014, Cipla in-licensed a second biosimilar, 'Darbepoetin alfa', by entering a co-marketing deal with Hetero Drugs, an Indian biotech company.

In 2012, a new management team initiated a strategy to convert the various partnerships into subsidiaries and joint ventures to bolster complimentary capabilities. In 2012, Cipla acquired its distribution partner in South Africa and increased its stake in a Uganda-based joint venture. In 2013, Cipla acquired a 100% stake in its Croatian distributor, a 51% stake in its UAE distributor and a 60% stake in a pharmaceutical company based in Sri Lanka. Cipla aims to start selling both its biosimilar products in international markets using these newly acquired marketing and distribution entities.

**Fig 2 Cipla Laboratories Ltd**



In the biosimilar market Cipla is creating a product portfolio through in-licensing and investing in expanding its international presence by converting its existing partnerships into company owned subsidiaries. This indicates that the company is using its strong complimentary capabilities in the form of sales and distribution infrastructure while depending on partnerships and acquisitions for creating a biosimilar portfolio.

### **5.3 Dr Reddy's Laboratories (DRL): A biopharmaceutical firm**

DRL was founded in 1984 by Dr Anji Reddy with the aim of creating an innovative Indian pharmaceutical company. DRL set up biotechnology R&D in 1999 as a separate business unit and within two years launched its first biosimilar product, Filgrastim. In 2003, this effort received a boost with the hiring of Dr Cartikeya Reddy from Genentech Corporation as head of the Biological division. Reddy helped DRL to accelerate the development of its biosimilar business and in a period of 10 years succeeded in launching three more biosimilars; Darbepoetin Alfa, Pegfilgrastim and more significantly Rituximab. Rituximab, launched in 2007, DRL was a milestone for the company in terms of its biosimilar program as it was their first monoclonal antibody for cancer and it made DRL the first company anywhere in the world to produce a biosimilar referencing Roche's originator \$6 billion cancer drug MabThera (fig 3).

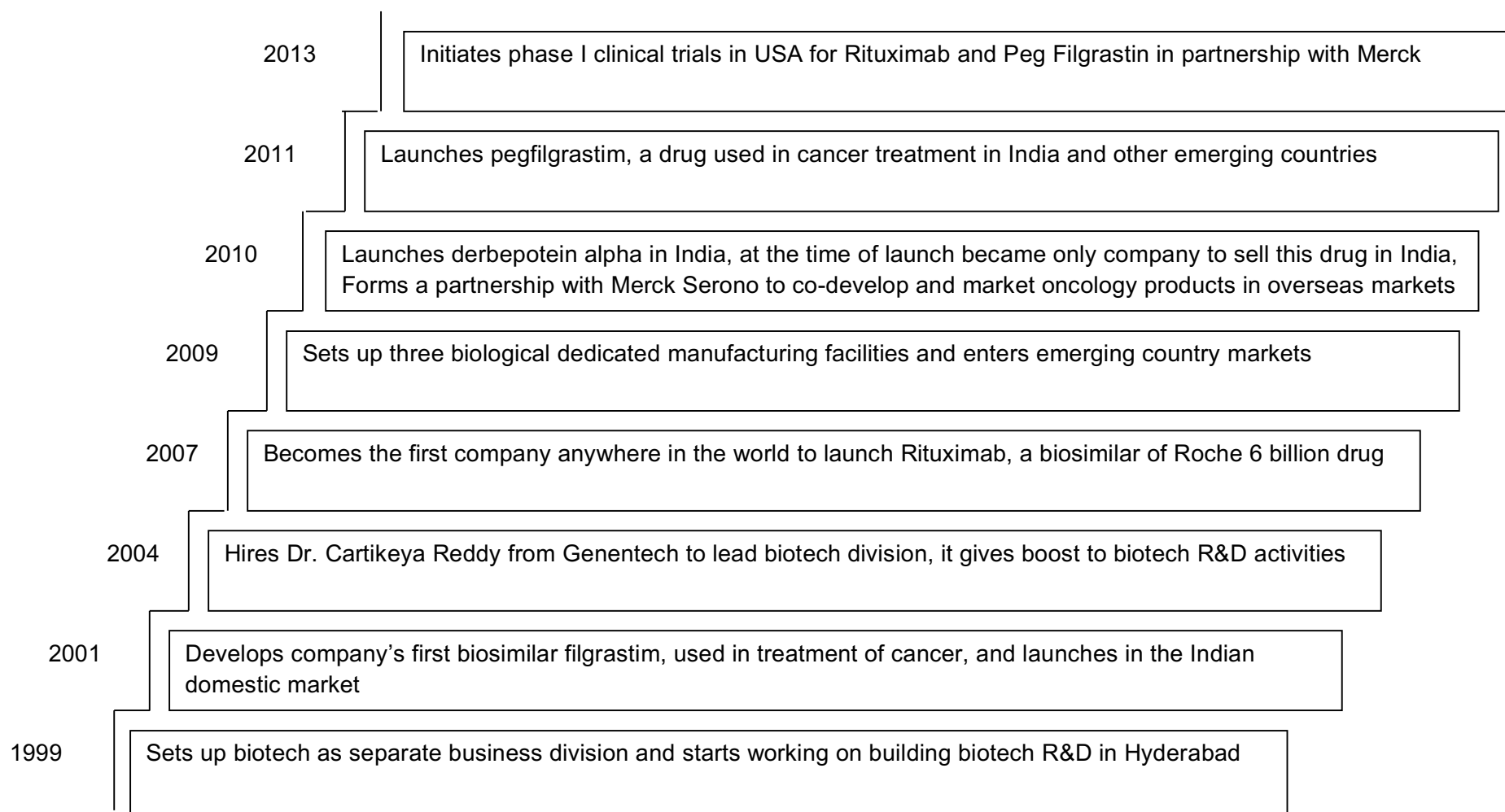
Gradually, DRL increased R&D investments for its biological division and by 2014, it reached 35% of total R&D expenses. By 2010, DRL was operating with three biological dedicated manufacturing facilities and a team of more than 300 scientists and engineers. At this stage, DRL adopted a strategy of commercialising its biosimilars in emerging markets as a step towards gaining approval in the US and Europe. This strategy allowed DRL two advantages. First, it helped the company to gather crucial real world experience and clinical data on the performance of its products and, second, it provided DRL an opportunity to generate revenue that could be utilised for developing drugs for advanced countries. Following on, in 2010, DRL began selling Rituximab in emerging markets at a 30-50% discount compared to the innovator brand.

In 2012, DRL started planning to enter the highly regulated US and European markets. As part of that strategy, in June 2012, DRL formed an alliance with Merck Serono, a division of Merck KGaA, Germany, Merck KGaA is a global pharmaceutical company with proven expertise in developing, manufacturing, and commercialising biopharmaceuticals and chemical

compounds. The partnership aimed to co-develop and globally commercialise a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (mAbs). The alliance allowed DRL to mitigate the risks involved in developing a biosimilar (a cost estimated at \$100-200 million). By 2013 DRL started applying for FDA and EMA approval. In 2013, the company filed a US investigational new drug (IND) application for its Rituximab biosimilar and peg-filgrastim and received permission to proceed with the Phase-I trials in 2014. At present, DRL is involved in planning, designing and executing clinical studies under these INDs.



**Fig 3 Dr Reddys Laboratories Ltd**



## **6.0 Analysis and discussion**

The firms in this study show the employment of different strategies that integrate, build and reconfigure internal and external competencies to address the changing environment. In other words, the development of dynamic capabilities.

### **6.1 Strategies that develop technological capabilities**

The case study evidence summarised in Table 2, lists the main activities that we have linked to increasing capabilities in biosimilars and the strategies employed to gain these. Analysis of Indian firms biosimilar product portfolios reveals that manufacturing capabilities and not the therapeutic class, form the basis of specialisation, cost and knowledge advantage. These firms are balancing risk in biosimilar production and marketing by building a very wide biosimilar portfolio covering several therapeutic areas and promising candidates. Regulatory handling capabilities are concerned with preparation of safety, quality and efficacy data, in a format required by regulatory authorities.

**Table 2 Technological Capabilities for biosimilar development (Annual Reports, 2013; Analysts presentation, company reports)**

	<b>Biocon</b>	<b>Cipla</b>	<b>DRL</b>
<b>Biotechnology R&amp;D</b>	1999	2010	1999
<b>Dedicated Biological R&amp;D</b>	Bangalore, India	Goa, India	Hyderabad, India
<b>Biosimilar manufacturing capabilities</b>	Integrated facilities in India and Malaysia		Integrated facility in India
<b>Key R&amp;D acquisitions</b>	Acquisition of Cuban company CIMAB's 49% stake in their joint venture, Biocon Biopharmaceuticals Pvt Ltd (BBPL) in 2010	Acquisition of Mabpharm, an Indian biotech company, Acquisition of 25% stake in BioMab, a Shanghai based biotech company.	
<b>In-licensing of biosimilars</b>		2	
<b>Clinical trials/ Clinical Research organisation</b>	Clinigene, in-house CRO established in 2000.		Partnership with CRO Argenta (UK)

Table 2 shows that all firms have invested in the development of biosimilar capabilities by setting up dedicated biosimilar R&D and manufacturing facilities. This has created a basic knowledge base for identifying and acquiring knowledge from external sources.

Firms in our study lack certain R&D resources in-house to carry out activities such as bioprocess development and cell-line development. These firms have adopted a combination of

three strategies to fill these gaps: i) increasing R&D investments and setting up in-house clinical research organisations (CRO), ii) establishing collaborations with overseas firms and research institutes and iii) hiring scientists with extensive experience of biotech R&D.

Increasing R&D investments and setting up in-house clinical research organisations was notably accomplished by DRL which established biotech as a separate business division and invested in building separate R&D facilities. One senior R&D manager at DRL commented:

“When we started we knew this represented totally a new capability, only few companies have done it and only few companies knew how to do it. So I think we pursued it with that understanding and therefore acted on it like we want to build a new set up from scratch. And to me that’s really what served us well. We didn’t think of it as a business plan, we didn’t think of it as a product, even while we obviously had business plan that drove the investment. The end game was not about when I get revenue out of the next molecule because if you look at it that way then there is no reason to invest in this. The only way this entire investment makes sense is to understand that it represents a huge proportion of pharma pipeline and you are running it as a right to participate in the new segment of the industry.” (Interview/2014)

Biocon also set up an in-house CRO to develop absorptive capacity in biosimilar commercialisation. DRL on the other hand has preferred to out license biosimilar clinical trials rather than investing in in-house building of these complimentary capabilities.

Strategies which involve establishing collaborations with overseas firms and research institutes, particularly in advanced countries allow firms to tap into external knowledge sources, fill knowledge gaps and reduce development costs. This is exemplified by the early starters DRL and Biocon, which developed collaborations to develop basic capabilities in biological R&D. (Table 3).

**Table 3 Key R&D collaborations (Annual reports, company website)**

<b>Year</b>	<b>Indian firm</b>	<b>MNC</b>	<b>Nature of alliance</b>

2004	Biocon	Vaccinex (USA)	Co-develop at least four therapeutic antibody products
2006	Biocon	Cuban Institute of Molecular Immunology (CUBA)	Development of antibody for treating cancer
2007	Biocon	Abraxis (USA)	Filgrastim GCSF (product development and marketing)
2009	Biocon	Amylin	Co-development of novel peptide hybriide for treatment of diabetes.
2009	Biocon	Mylan (USA)	Co-development of five MABs
2010	Biocon	Pfizer (USA)	Insulin and analogues (Pfizer: marketing and sales)
2012	DRL	Merck Serono (Switzerland)	MABs (joint development)
2014	Biocon	Advaxis Inc (USA)	Co-development of its lead drug candidate

A typical strategy involves Indian firms handling early product development and early stage clinical trials, while overseas firms produce the compound and handle late-stage clinical trials. An R&D head at a leading firm commented,

“Most companies might say that they are collaborating because it’s expensive but truth is that they are collaborating because it’s difficult. All the capabilities needed are practically like a full-fledged pharma company but what you are doing is biosimilar. And that’s the dilemma. From Pfizer to virtual biotech company based in San Francisco have something to offer. Now we are focusing on more global development efforts so we are investing in technologies, investing in partnerships that can give us some late stage capabilities and that can help us access markets like the US and Europe.”

This finding suggests that firm level dynamic capability development cannot happen in isolation and external linkages with other firms formed a key part of Indian firms’ dynamic capability development strategies, even though the nature and motive of their relationships differs in each firm.

The strategic hiring of scientists as demonstrated by all case studies, allows firms to acquire specific knowledge in biosimilar production, development and regulation. Analysis suggests clear differences however, in Cipla's motives for hiring compared to other case study firms. Cipla's hiring is focused on filling top management positions in marketing, regional markets and strategy while hiring in other firms is targeted towards improving biotechnology R&D knowledge. This corresponds to Cipla's strategy of building a biosimilar business model around strengths in marketing and distribution capabilities.

## 6.2 Strategies that develop market capabilities

This section considers the capabilities required in the downstream post market phase. In assessing market capabilities, factors include; the global diversity of a company's markets, management of the product portfolio in each therapeutic segment, presence of distribution and sales network infrastructure and the ability to create local partnerships to facilitate market entry. Table 4, lists the factors present in the data, that indicate market capability in biosimilars and the strategies employed to gain these capabilities.

**Table 4 Market capabilities: Entry into international markets and partnerships (Annual Reports, 2013)**

	Biocon	Cipla	DRL
<b>Biosimilars marketed in India</b>	7	1	4
<b>Biosimilars sold in emerging country markets</b>	Insulin in 40 countries and Glaringe insulin in 5 countries		Presence in small 13 emerging markets with local partners
<b>Biosimilars marketed in advanced countries</b>	Completed Phase III trials in EU for Glaringe insulin		Phase I clinical trials in USA for Rituximab and Peg Filgrastin in partnership with Merck

<b>Market sharing agreements with overseas firms</b>	Partnership with Pfizer (2009-2012) Partnership with Mylan (2010) Partnership with CCM pharma to enter Malaysian and Brunei markets (2013)		Collaboration with Merck Serono to enter Europe market by 2017
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Indian firms have extensive presence in advanced country markets whether measured through their exporting or foreign investment activities (Table 4). The marketing capabilities and strategies used for entering international small molecule generics market have provided these Indian firms a vital springboard to enter international biosimilar markets. Cipla, and DRL for example have long established marketing and distribution networks. This has created significant complimentary capabilities (Teece, 1986) and in-depth understanding of the overseas market which facilitates entry of Indian firms into international biosimilar markets. Evidence points to Indian firms reverting to strategies prevalent amongst pharma firms in the pre -1990 era; targeting the rest of the world (excluding advanced country markets) and domestic markets for growth. The Head of Strategy of a leading Indian firm points out,

“Taking the emerging country market route helps us do two things: one, stay close to our purpose of accelerating access to affordable biosimilars in emerging countries and second, to access short term revenue that de-risks our business journey and makes business more sustainable.” (Interview/2014)

Couched in a more socially conscious rhetoric there is a simple strategy of entering the market and reducing the rent of a monopoly supplier when patent protection has been removed. The more compelling question is why emerging country markets are initially targeted when reimbursement structures and higher prices in advanced country markets offer higher returns. The evolving nature of regulatory systems in advanced country markets and demands for extensive data creates a higher level of risk and investment for Indian firms. A regulatory head comments,

“It’s really accumulating that evidence that costs money. To compete in the US and Europe you need that money and it is highly unlikely that an Indian firm can do that across multiple products as it will break the R&D budget of any Indian firm.”  
(Interview, 2014)

The strategy of targeting emerging markets additionally offers Indian firms opportunities to collect necessary clinical data on safety, which may aid the application to regulatory authorities in the West.

Table 4 reveals some key subtle differences in terms of modes of entry used by each firm to internationalise their biosimilar business. It suggests that Indian firms used three different routes for setting up of manufacturing facilities in overseas countries: greenfield investments, acquisitions and joint ventures. Biocon is using green field investment and the partnership route while Cipla is adopting the acquisition route to expand in overseas markets. Biocon has set up a manufacturing plant in Malaysia and established a partnership with Mylan and other firms to serve advanced country and other emerging country markets. In contrast Cipla is acquiring a stake in other biotech firms and converting many of its existing overseas partnerships in manufacturing, sales and distribution into its own subsidiaries through equity deals and joint ventures.

### **6.3 Heterogeneity in business models; path dependence versus managerial vision**

Finally, case study analysis shows evidence of a relationship between managerial vision and heterogeneity observed in firms. Trajectories of the firms are partly shaped by path dependencies, but also by the disruptive forces created by new managerial strategies and the expansion of firms into the biosimilar area.

In transitioning to biosimilars, the firms chose different paths – Biocon and DRL are adopting an organic route of investing in R&D, collaborating with overseas firms and building strong human resources, and Cipla through an in-licensing, acquisition and joint venture route. Biocon and DRL adopted an organic growth model based on building strong upstream drug development capabilities. Biocon was a biotechnology company from the beginning and set up a clinical research organisation, which created path dependency and complementary competencies. Similarly, DRL has shown strong technological capabilities in biotechnology



R&D evidenced by its product portfolio. In contrast, Cipla focused on an acquisition model with pre-existing capabilities in marketing and distribution. Cipla lacked experience of reverse engineering large and complex molecules but was driven by strong cash flow, ambitious leadership and well-established marketing networks in advanced countries. Cipla is compensating for a lack of R&D capabilities by in-licencing technology and products from overseas firms and using existing distribution and marketing capabilities to build their biosimilar business.

These differences in strategy both give rise to, and result from, capabilities acquired through different means. Evidence highlights significance of complimentary capabilities but also reveals that some pre-existing capabilities learned through experience with small molecule generics markets constrained development of biosimilar R&D and regulatory capabilities. All firms under study invested in setting up new R&D infrastructure, organisational practices and regulatory capabilities as existing infrastructure and practices became secondary, though not completely obsolete in the new environment. Studies of other industries suggest that some resources, processes and capabilities that served firms well in the past become obsolete where there is a new technology and discarding these activities forms important aspect of adding new knowledge (Leonard-Barton, 1992). With biosimilars, a significant degree of risk is evident in the projected future growth of the market, the evolving regulation and the position of emerging country suppliers. Biosimilar capabilities are therefore being developed in parallel with small molecule generics. This means that biosimilars will likely be developed by large firms which have sufficient resources and capabilities to employ either the organic or acquisition strategies that we identify.

While existing technological competence played an important role as did the firms' historical trajectories, two other factors also have important roles to play in defining the strategy mixes adopted by Indian biosimilar producers: primarily 'firm specific managerial dynamic capabilities', and also 'inter-organisational learning' through the observation of compatriot leader firms. Firm specific dynamic managerial capabilities are thus driving reconfiguration strategies and shaping firm level technological learning in Indian firms. The vision of Dr Yosuf Hamied that Cipla could be a significant global player in biosimilars led to change in the management team and drove the company's ambitious acquisition strategy. Further Dr Hamied's focus on cheap drugs and disbelief in strong patent laws lies at the heart of acquisition

focused strategy adopted by Cipla. In contrast, Biocon and DRL are guided by R&D focused visions of Kiran Muzumdar Shaw and Dr Anji Reddy respectively. Biocon's direction was guided by the ambition of Kiran Muzumdar Shaw to draw global recognition for Indian firms in the biotechnology sector. Anji Reddy's aim was to take DRL into the top ten of global pharmaceutical companies and he believed that this could be done through innovative R&D. These leaders have knowledge and expertise to sense opportunities and reconfigure organisational resources, competencies and structures, reinforcing significance of dynamic managerial capabilities in influencing strategic change (Helfat and Martin, 2015).

Firms chose different paths and business models to create a market- technological capabilities mix, however, the strategies firms have used to achieve these transitions have also been borrowed from each other. Late entrant Cipla is following early entrant Biocon's example and has invested in the development of complimentary capabilities by setting up clinical research organisations (CRO's). De-risking biosimilar investment through targeting emerging country markets was initiated by Biocon but is now followed by other Indian firms. It suggests that inter-organisational learning through observation of other firms' successful strategies, has significantly influenced the strategies pursued by firms and may be as important as own firm learning. In this sense the heterogeneity in business models and inter-organisational learning initiated by firms constitute a search and experiment exercise for the whole industry.

## **7.0 Conclusion**

Analysis of heterogeneity in strategies to exploit biosimilar opportunities points towards an evolution of Indian firms' capabilities throughout the production process, starting from upstream expansion of the knowledge base and re-orientation of R&D to downstream enhancement of partnership and marketing capabilities in emerging markets. It is evident that Indian firms are reconfiguring existing strategies by targetting emerging country markets to de-risk their investments and entering into collaborations and partnerships with overseas firms and research institutes to augment their own capabilities.

We have attempted to draw a distinction and show how managerial vision contributes to the development of other capabilities in the firm. The influential role played by firm specific dynamic managerial capabilities in shaping firm strategies highlights and reinforces the link between heterogeneity and managerial capabilities (Helfat and Martin, 2015). The link is a

complex interrelationship with one set of capabilities influencing another. Evidence suggests that learning processes and business models in case study firms are clearly shaped by owners with strong vision and beliefs. For example, DRL and Biocon models reflect R&D focused vision of Dr Reddy and Kiran Muzumdar Shaw while Cipla is following Dr Hamied's vision of aggressive entry into emerging country markets. This reinforces Helfat and Martin's (2015) argument that the dynamic managerial capabilities concept provides a broad lens for understanding managerial impact on strategic change across a wide range of settings.

Most probably the winning combination will include certain elements of the different models and will prove to be a robust way in which to overcome the key challenges of talent unavailability and resource constraints. However evidence from this research does point towards the emergence of the organic growth model as the dominant and long term growth model for Indian and other emerging country firms. These insights have strategic implications for generic pharmaceutical firms operating in other advanced and emerging countries.

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